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VIA ECF

Special Master the Honorable Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower
18th Floor
Philadelphia, PA 19103

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Special Master Vanaskie:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Biweekly Teleconference with Your Honor on July 13, 2022. The parties do not expect the need to discuss any confidential materials as part of these agenda items.

1. Plaintiffs' Request to Expand the Scope of the Core Discovery for Losartan/Irbesartan to Include "All nitrosamine testing"

The parties met and conferred on July 1 and again on July 7 over Plaintiffs' proposed categories of losartan/irbesartan "core discovery." Based on these discussions, Defendants believe the only issue requiring the Court's attention before finalizing a proposed core discovery order for these products relates to Plaintiffs' request that production of "all nitrosamine testing" be prioritized from the custodial document review and production and added to core discovery. (*See* Proposed Order attached at Exh. A).

As an initial matter, Defendants have not objected to the inclusion of any items that were requested and ordered for production as part of valsartan core discovery on April 29, 2019. [*See*

ECF No. 88]. The meet-and-confer process on those materials has strictly involved clarifying and incorporating later rulings into the proposed order so that the parties can avoid returning to the Court for further discussion of issues that have been previously resolved. Moreover, Defendants have not objected to Plaintiffs' request for an expanded core discovery order that also includes: (1) production of certain FDA correspondence and documentation that was ordered for production in December 2019 and produced in early 2020; and (2) sales and pricing information that was not produced until May 2020. However, Plaintiffs' expansive request for "all nitrosamine testing" dramatically broadens the prior core discovery order and rulings and effectively requires Defendants to undertake the type of comprehensive document review that was not completed until November 2020 – approximately 18 months after entry of the valsartan core discovery order – on a drastically accelerated timeline. This added request does not comport with the spirit and intent of "core discovery."

Defendants proposed that production of a limited set of readily-identifiable testing information, including all data provided to the FDA in connection with the losartan and irbesartan recalls, could be added to the expanded core discovery order. These testing data, along with the publicly available information on which lots of Defendants' products have been recalled due to the presence of certain impurities, will provide Plaintiffs with the basic understanding needed to formulate later discovery. Plaintiffs objected to this proposal but have not narrowed their request for "all nitrosamine testing" in an attempt to reach compromise. It is notable that "all nitrosamine testing" directly encompasses information that was ordered for production as part of the custodial document production across no less than 4 specific Requests for Production, (*see* Doc. 328 Exh. A, RFPs 21, 36, 37, 46), and at least arguably requires Defendants to identify and produce material

requested in 20 other RFPs, (*see id.* RFPs 4, 5, 6, 10, 22, 25, 26, 29, 30, 35, 40, 42, 44 and 45-51). Final production of material responsive to these document requests did not occur until November 2020. Adding this expansive item to core discovery will require Defendants, a number of whom have not previously participated in any discovery because they were not involved in the valsartan cases, to undertake a similarly comprehensive document review on a greatly accelerated timeline.

In keeping with the spirit and intent of core discovery as established for the valsartan cases, the Court should enter Defendants' proposed order, which incorporates language limiting the scope of testing to be produced to information provided to the FDA in connection with the recalls.

2. Plaintiffs' Proposed Case Management Plan

At the June conference with Judge Kugler, counsel for Plaintiffs indicated their intent to file certain motions for summary judgment, including, for example, with respect to their claims for breach of express warranty, violation of state consumer-protection statutes and violation of CGMP. (*See* June 1 Hr'g Tr. 14:18-23.) In response to this proposal, the Court stated: "[C]learly the plaintiffs in their motions for summary judgment are going to have to identify the exact claim they're seeking summary judgment on and the statutes in that particular jurisdiction that are implicated." (*Id.* 27:19-22.) When defense counsel expressed "hope" that "we could get to a place where the schedule contemplates a ***plaintiff*** and a state law," the Court stated: "Well, I think that's what's going to happen. And obviously, if it doesn't, you know, we'll fix it." (*Id.* 28:4-13 (emphasis added).) The import of the Court's statements is clear: counsel must identify the particular plaintiffs whose claims will be the subject of any dispositive motion practice so that Defendants can undertake any necessary discovery, identify proper experts and be prepared to brief the issues under the right facts and right state law. The Court also encouraged the parties to

focus on one or more of the individual third-party payor economic loss plaintiffs given that class certification motions are still pending.

Consistent with those pronouncements, (and without waiving Defendants' objections to this entire proposal), Defendants repeatedly reached out to Plaintiffs' counsel (first by conference call and then by follow-up email correspondence) seeking a list of cases whose claims will be the subject of merits discovery and subsequent dispositive motion practice. However, counsel for Plaintiffs have taken the position that the parties can proceed with discovery and summary judgment briefing "targeted at the allegations of the master complaints" with no further clarification. (July 7 Email from A. Slater to J. Miller, attached as Exh. B). Because there is no certified class action in this case, that response is simply too vague to protect Defendants' due process right to defend against Plaintiffs' contemplated motions.

As the Court is aware, the Master Complaints were filed by numerous plaintiffs from across the country, implicating the laws of different states and territories. At this point, pursuant to choice-of-law rules, the parties would have to undertake the herculean task of briefing summary judgment under the disparate laws of all these states and territories, resulting in thousands of pages of briefing. Otherwise, Plaintiffs would essentially be seeking to "impose ***global*** MDL liability on the Defendants" in the abstract—untethered to any particular claimant. *See, e.g., In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 20-MD-2924, 2021 WL 3473759, at *2-3 (S.D. Fla. Aug. 6, 2021) ("Should the Plaintiffs survive the Defendants' *Daubert* challenges, then, at the proper time, ***an individual Plaintiff*** may seek to pursue his or her individualized negligence claim against a Retailer or Distributor Defendant.") (second emphasis added); *see also, e.g., Kohn v. Am. Hous. Found., Inc.*, 178 F.R.D. 536, 542-43 (D. Colo. 1998) ("[T]he liability issue cannot be decided in

the abstract . . . ."); *Ballew v. Matrixx Initiatives, Inc.*, No. CV-07-267-RHW, 2008 WL 4831481, at *3 (E.D. Wash. Oct. 31, 2018) ("The [c]ourt should not certify a class based on this broad, abstract question. . . . Answering this question resolves no class member's claim and only invites the difficult question of how to proceed once the question is answered.") (citation omitted). For these reasons, Defendants need clarity as soon as possible, particularly since Defendants will need to conduct discovery on the specific cases and claims that Plaintiffs intend to place at issue before any dispositive motions can be briefed.[1]

Accordingly, Defendants respectfully request that the Court order Plaintiffs' counsel to identify the particular cases in which Plaintiffs will be moving for summary judgment.

3. Attendance at Court-Ordered Mediations

Judge Kugler previously ordered that settlement counsel for API Manufacturers and for Wholesalers attend settlement conferences set before the Settlement Masters, Judge (Ret.) Sleet and Judge (Ret.) Stengel on August 26, 2022, and September 15, 2022, respectively. [ECF Nos. 2100 and 2101]. Plaintiffs seek to ask Judge Kugler to expand his orders to now include certain finished dose manufacturers at these upcoming settlement conferences. While settlement counsel for the Finished Dose Manufacturers stand ready to follow the Court's further direction with respect to the timing and participation in any forthcoming settlement activities, Defendants expect

[1] Contrary to Plaintiffs' counsel's suggestion, Defendants' position is not inconsistent with their prior approach to moving to dismiss the master complaints. As the Court recognized, "neither party squarely addressed" "the appropriate law to apply to each of plaintiffs' claims." *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 2875 (RBK/KW), 2021 U.S. Dist. LEXIS 17728, at *49 (D.N.J. Jan. 29, 2021). Moreover, as the Court further explained, such a choice-of-law analysis requires application of "the law of the plaintiff's home state," *id.* at *55-56, underscoring the importance of identifying which plaintiffs will be moving for summary judgment in this litigation.

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Judge Kugler's orders were intentionally crafted in this way to provide some measure of organization to this process and that Judge Kugler will issue further orders with respect to the Finished Dose Manufacturers when Judge Kugler and the Settlement Masters feel they will be most productive.

Respectfully submitted,

/s/ Lori G. Cohen

Lori G. Cohen

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica D. Miller, Esq. (*via email, for distribution to Defendants' Counsel*)
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